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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,669	12/24/1999	JOHN P. ANDERSON	00228-US-NEW	7795

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

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06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/471,669	Applicant(s) ANDERSON ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 130-137, 178-182 and 335-338 is/are rejected.
- 7) ☒ Claim(s) 339-353 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims pending in the application are 48,51-62,64-69,114-182,184-188,190-194,196-200,202-206,208-212,214-218,220-224 and 226-391.

Continuation of Disposition of Claims: Claims allowed are 48, 51-62, 64-69, 114-129,138-177,184-188,190-194, 196-200, 202-206, 208-212, 214-218, 220-224, 226-334 and 354-391.

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In the amendment filed June April 10, 2997 is acknowledged. Claims 1-47 have been cancelled by the current amendment; claims 49-50, 63, 70-113, 183, 189,195, 201, 207, 213, 219 and 225 have been previously cancelled.

Claims 48, 53, 58, 64, 117, 125, 130, 133, 138, 141, 149, 154, 157, 165, 173, 190, 192, 196, 206, 208, 240, 259, 278, 286, 297, 304, 305, 306, 316, 335, 354 and 373 have been amended. Claims 48, 51-62, 64-69, 114-182, 184-188, 190-194, 196-200, 202-206, 208-212, 214-218, 220-224 and 226-391 are pending and under examination.

Detailed Action

Objections

Objections to claim 130, 192, 206, 286, 304, and 306 made in the Office Action of Dec. 5, 2006 (previous action) **are withdrawn**, because of the amendments.

Claim 178, line 4, misses "under" before "conditions".

Rejections

35 U.S.C. 112, second paragraph

Claims 53-57, claim 64-69, claim 117-121, claim 125-129, 133-137, 141-145, 149-153, 157-161, 165-169, 173-177, 240, 259, 278, 297, 316, 335, 354, 373 were rejected in the previous action as confusing as to whether the heterologous transfected cell is in a transgenic animal or it is an isolated heterologous cell, and because claims 335 and 354 were unclear as to the language of part (i). The rejection **is withdrawn**, because the claims have been amended.

Claims 130-137 are rejected as confusing, because SEQ ID NO: 63 is not a sequence of a beta secretase. The proper number of the amino acid sequence recited by claim 130 should be SEQ ID NO: 66; see claims 190-194 and 278-296 claiming other subject matter related to DNA molecule encoding SEQ ID NO: 66.

35 U.S.C. 102

A. *DNA molecules encoding beta secretase having amino acid sequence shorter than SEQ ID NO: 2*

A1. Claims 48, 51-57, 130-137, 138-145 and 154-161 were rejected as anticipated by the US Patent 6, 420,534 issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998. **This rejection is now withdrawn**, because the claims were amended by limiting their scope as examiner suggested, to an isolated nucleic acid consisting of a nucleotide sequence encoding the beta secretase consisting of SEQ ID NO: 43 (66, 67, and 69) or a perfectly complementary sequence thereof.

Response to applicants' comment

In REMARKS, page 38/39, paragraph 2.3A, applicants state, "However, applicant has further characterized the isolated nucleic acid by the recital encoding a beta secretase to make clear that "consisting of" transition following nucleic acid applies to the nucleic acid encoding a beta secretase and does not exclude the presence of

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unrelated (e.g. vector sequences) as are in fact recited to be present in dependent claims.

Claim 48 and parallel claims that are directed to SEQ ID NO: 66, 67 and 69 are allowed in their present form. However, the language of claim 48 does not include vector sequences in the scope of the claim. Claim 51, and the corresponding vector claims that are directed to vectors including SEQ ID NOs: 66, 67 and 69, are directed to an expression vector comprising the nucleic acid consisting of the sequence encoding beta secretase consisting of SEQ ID NOs: 43, 66, 67 and 69, and for that reason include vector nucleotides in their scope.

B. Method of producing a recombinant beta secretase shorter than SEQ ID NO: 2

Claims 58, 190, 196 and 208 were rejected in the previous action over Gurney et al as directed to a method of producing a recombinant beta-secretase enzyme by a cell transfected with a vector comprising a nucleotide sequence encoding the beta secretase consisting of SEQ ID NO: 43 (66, 67, 69). **This rejection is now withdrawn** because the claims have been amended.

35 USC 103

Heterologous cell comprising beta secretase DNA and beta secretase substrate DNA

Claims 64-67 (SEQ ID NO: 43); 278-281 (SEQ ID NO: 66); 297-300 (SEQ ID NO: 67); 335-338 (SEQ ID NO: 69) were rejected under 35 U.S.C. 103(a) as being unpatentable over Patent 6,420,534 issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 and a routine practice in the art of expressing enzymes in heterologous cells.

Rejection of claims 64-67 (SEQ ID NO: 43); 278-281 (SEQ ID NO: 66); 297-300 (SEQ ID NO: 67) is withdrawn, because the claims have been amended. Claim 335 has not been amended and claims 335-338 are still rejected.

Claims 339-353 are objected to as depending on claim 335 rejected under this paragraph.

Method of producing and purifying recombinant beta secretase shorter than SEQ ID NO: 2

Claims 61, 193, 199 and 211 were rejected under 35 U.S.C. 103(a) as being unpatentable over Patent 6,420,534 issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 and a routine practice of protein purification using affinity matrix, wherein affinity matrix contains antibodies having abilities to bind said protein. **Rejection of claims 61, 193, 199 and 211 is withdrawn** because the base claims 58, 190, 196 and 208 have been amended.

Double patenting rejection

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Provisional obviousness type double patenting

Claim 178-182 are rejected as being obvious over claim 168 of the allowed US patent application No. 11/090,399. Claim 168 is directed to a method of production of SEQ ID NO: 58 wherein the isolation of protein encompasses any method of isolating. Claims 178-182 of the instant application are directed to the same subject matter wherein the isolating the protein is achieved using affinity matrix, wherein the matrix contains beta secretase inhibitor of SEQ ID NO: 83, beta-secrase specific antibodies, and an antibodies specific for SEQ ID NO: 58. The method of isolating listed by claims 178-182 of the instant application are species of the genus of isolating methods recited by claim 168 of 11/090,399. All methods recited by claims 178-182 are disclosed in the specification of application No. 11/090,399. Thus using them for purification of SEQ ID NO: 58 would be obvious.

Conclusion

The following claims are allowed:

48-69, 114-129, 138-177, 184-188, 190-200, 202-206, 208-212, 214-218, 220-224, 226-334, 354-391.

The following claims are rejected:

130-137, 178-182, 335-338,

The following claim are objected to:

339-353.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner


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